# vaccibody

**ABGSC Life Science Summit** 

May 25, 2021



# Forward-looking statement

This announcement and any materials distributed in connection with this presentation may contain certain forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect the company's current expectations and assumptions as to future events and circumstances that may not prove accurate.

A number of material factors could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements.

### **Today's presenters**

**CEO**Michael Engsig



M.Sc. Biochemistry and G.D.Bus.Admin.

- Extensive experience from leading early-stage drug discovery through late-stage and commercial development
- Launched products across all major geographical areas
  - · Takeda and Nycomed
  - PPD
  - KLIFO

**President & Chief Scientific Officer** Agnete B. Fredriksen



M.Sc. in Molecular Biology and Ph.D. in Immunology

- Designed and created the first Vaccibody molecules
- Co-founder of Vaccibody AS (2007)
- Served as CSO since 2007



## **Overview of Vaccibody**

- Leading vaccine platform taking advantage of differentiated technology to address a broad range of diseases
- Highly advanced oncology pipeline with two Phase 2 assets including VB10.NEO, an individualized vaccine targeting tumor specific epitopes, as well as VB10.16, an off the shelf vaccine
- Rapidly advancing infectious disease platform with initial focus on COVID-19 validating our approach
- Significant collaboration with Genentech to support development of key assets
- Highly experienced management team with track record of success



## Vaccibody's Strategy

Leveraging Vaccibody's validated technology platform for maximum value generation

Vaccibody's aim is to become the world's leading vaccine technology company with an ability to address a range of diseases by executing on the core tenets of its strategy:



Rapidly advance existing assets through the clinic



Further leverage the technology platform to expand pipeline



Seek strategic partnerships to compliment our strengths



# Strengthening the Management Team to prepare for future growth journey

Vaccibody hires new CFO and a new Chief Scientific Officer.

Agnete B. Fredriksen to transition to role as Chief Innovation & Strategy Officer from June 1, 2021

**CFO** Harald Gurvin



M.Sc. in Shipping, Trade and Finance, and MSc in Marine Engineering and Naval Architecture.

- Long track record in international CFO positions (most recently as CFO in Flex LNG)
- Solid experience with US capital markets and listings

CSO (per June 1, 2021) Mikkel W. Pedersen



M.Sc. In Human Biology and Ph.D. in Cancer

- Long experience in drug discovery and development
- · Previous role as CSO of Symphogen, a subsidiary of Servier
  - Discovering and developing antibody-based drugs for the treatment of cancer, inflammatory and infectious diseases.



## **Pipeline**

Broad oncology coverage and strong partnerships. Leveraging platform within infectious diseases

Program	Indication	Discovery	Preclinical	Phase I	Phase II	Phase III	Partnerships	
Oncology and precancer								
Individualized								
VB10.NEO	Melanoma, lung, bladder, renal, head & neck						Genentech <sup>1</sup> Nektar <sup>2</sup>	
VB10.NEO	Locally advanced and metastatic tumors						Genentech 1,3	
Off the shelf		1						
VB10.16	HPV16 positive cancers Cervical cancer <sup>4</sup>							
Undisclosed	Undisclosed targets within shared antigens	•						
Infectious disease								
VB10.COV2	SARS-CoV-2							
Undisclosed	Undisclosed targets within infectious disease							



## Flexible Vaccibody™ format can fuel multiple products customized for each indication

The Vaccibody™ technology platform is developed based on the concept of targeting antigen to Antigen Presenting Cells (APCs) in order to create more efficacious vaccines

#### Flexibility in the molecule



#### Vaccine modalities

The Vaccibody™ platform is agnostic in terms of delivery format:

- DNA vaccine
- mRNA vaccine
- Viral vector vaccine
- Protein subunit vaccine

The Vaccibody™ platform allows for flexibility both within the molecule and through the mode of delivery Safety - Vaccibody™ is very well tolerated across patient groups

Large potential for combining Vaccibody™ with other treatment regimens

## Vaccibody™ mechanism of action

The APC targeting vaccine technology platform creates unique rapid, strong and broad immune responses that can be tailored to each disease **Neutralization** APC -B cell of pathogen **APC** targeting and 4a 3a synapse **APC Needle-free injection &** attraction in-vivo expression Deltoid 3b

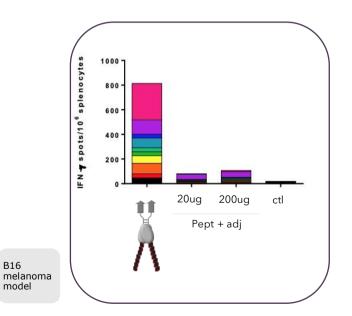


Internalization & presentation to CD4 and CD8 T cells

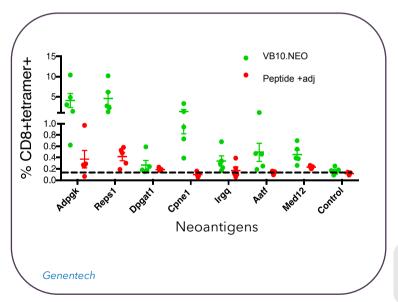
Killing of cancer cells or pathogen-infected cells

### Vaccibody induce rapid and strong T cell responses with unique increased breadth of the CD8 T cell response

**VB10.NEO** exhibits superior priming after single dose



#### VB10.NEO elicit a potent and broad **CD8 T cell response**



MC38 colon carcinoma model



B16

model

### VB10.NEO generates a broader immune response profile dominated by CD8+ T cells than competing technologies

B16 melanoma Pep 1 Pep 2 Pep 3 Pep 4 Pep 5 Pep 6 Pep 7 Pep 8 Pep 9 Pep10 model Peptide\* CD4 CD8 RNA\* CD4 CD8 Non-CD4 nt nt nt nt targeted CD8 DNA VB10.NEO CD4 CD8

Peptide and RNA vaccines induces primarily CD4 T cell responses, while VB10.NEO induces strong, dominating CD8 responses to the identical neoepitope sequences

Non-Confidential

Non-targetd DNA vaccines induced a CD8 response towards 1 of 6 tested neoepitopes

vaccibody

Castle et al., 2012 and Kreiter et al., 2015 · Aurisicchio et al., 2019

## **VB10.NEO: Exclusively licensed to Genentech**

Global, oncology collaboration between Vaccibody and Genentech to develop individualized neoantigen cancer vaccines across multiple tumor types



**Genentech**A Member of the Roche Group

Conduct clinical Phase1b trial combining VB10.NEO with atezolizumab



Responsible, and bear all costs, for all further clinical, regulatory, manufacturing and commercialization activities for VB10.NEO

Research, Bioinformatics and Manufacturing Collaboration

- Initial upfront and near-term payments of USD 200 million
- Potential milestone payments of up to USD 515 million
- Tiered low double-digit royalties on net sales

The Genentech collaboration was announced October 1st, 2020



Non-Confidential

12

# **VB10.NEO:** Vaccibody's individualized cancer vaccine - potentially best in class

Targeting antigen presenting cell

Proprietary neoantigen selection method

Promising immunogenicity and clinical data
Phase I/IIa in >50 patients with melanoma, NSCLC, SCCHN, RCC and urothelial cancer

• **Delivered as DNA plasmid**Flexible, rapid and cost-effective manufacturing
100% manufacturing success rate

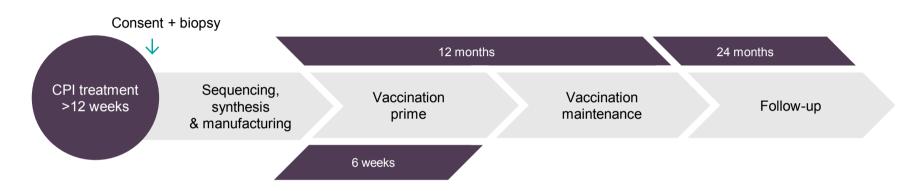
**VB10.NEO** 



Fully personalized vaccine against the patient's individual cancer specific mutations



# VB10.NEO: Trial design for VB N-01 facilitates efficacy readouts in each patient

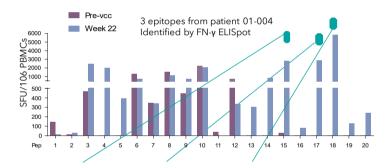


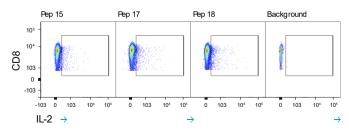
- Inclusion criteria: Previous treatment with checkpoint inhibitor for >12 weeks at enrollment
  - Late-stage cancer patients not responding optimally to CPI
  - With ~12 weeks manufacturing time, patients have been treated at least 6 months on CPI before 1<sup>st</sup> dose VB10.NEO
  - Limited tumor reduction expected from continuous checkpoint inhibitor treatment after 6 months



## VB10.NEO: Strong signs of clinical efficacy. Neoepitope-specific CD8 dominating immune responses in SCCHN patients with clinical response

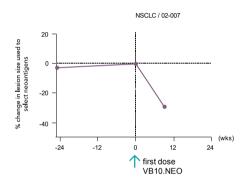
- Marked changes in lesion size development observed after initiating VB10.NEO
- Shrinkage of tumors and stabilization of progressing lesions
- Strong, dominant CD8 responses in patients with clinical responses



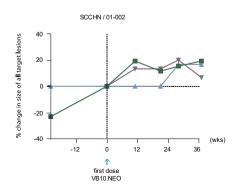


#### vaccibody

#### Stable disease at vaccination start



#### Progressive disease at vaccination start



# VB10.16: Therapeutic cancer DNA vaccine against HPV16 induced pre-malignancies and malignancies

Expanding the clinical development plans in multiple indications

C-01

- Finalized Phase 1/2a study with VB10.16 monotherapy in HPV16+ precancerous cervical lesions
- Strong correlation between HPV16-specific immune response and lesion size reduction
- Upregulation of PD-L1 in the lesions post vaccination, provides scientific rationale for combination with anti-PD-1/PD-L1 in cancer patients

C-02

- Phase II study of VB10.16 + atezolizumab in advanced cervical cancer has been initiated and recruitment is on track
- IA #1, performed after 10 patients passed 6 weeks of treatment showed no safety concerns and the trial continuous as planned

Exploring the commercial potential of VB10.16 for the treatment of additional HPV positive cancer indications like HNSCC

**VB10.16** 



Off the shelf vaccine targeting foreign viral antigens



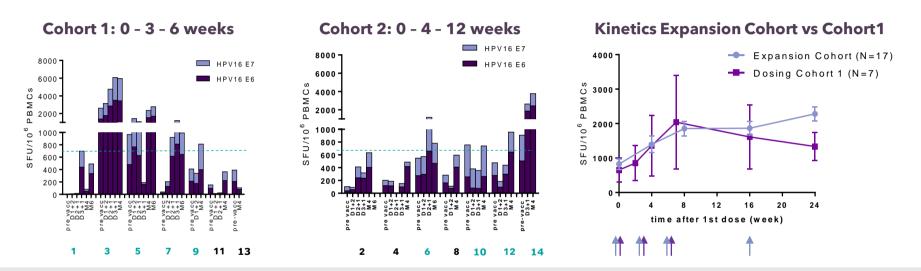
# VB C-01 trial: Therapeutic VB10.16 as monotherapy treating HPV16+ precancerous lesions



**VB C-01:** Exploratory, open labelled, multi-centre study in patients with HPV16<sup>+</sup> High Grade Cervical Intraepithelial Neoplasia (HSIL, CIN 2/3)

**Objectives:** To assess the safety/tolerability and immunogenicity and to make a preliminary assessment of clinical efficacy

## VB10.16: Strong correlation with strength of induced HPV16-specific immune response and lesion size reduction



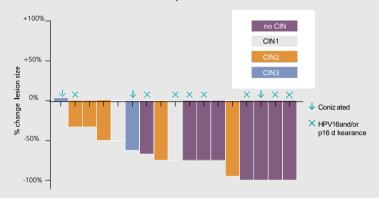
- All 9 patients with strong HPV16-specific T cell responses (>650 spots/mill) experienced reduction of the lesion size after vaccination with VB10.16
- The vaccination regimen from cohort 1 (week 0, 3 and 6) plus a booster vaccination at W16 was introduced in the Expansion Cohort. Stronger, long-lasting responses caused by the boost

# VB10.16: Strong clinical data as monotherapy in precancerous lesions

VB10.16 as a monotherapy in HPV16-positive, precancerous cervical lesions induces

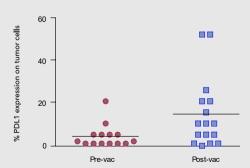
- Lesion size reduction in all patients followed >4 months
- CIN regression to CIN1 or no CIN in 10 patients
- HPV16 and/or p16 clearance in 8 patients
- Well tolerated, No SAEs
- Upregulation of PD-L1 in the lesions post vaccination, providing scientific rationale for combination with anti-PD-1/PD-L1 in cancer patients

Lesion size reduction, CIN regression and HPV16 and/or p16 clearance



Best response data (at enrollment: 10 CIN3 and 7 CIN2 patients)

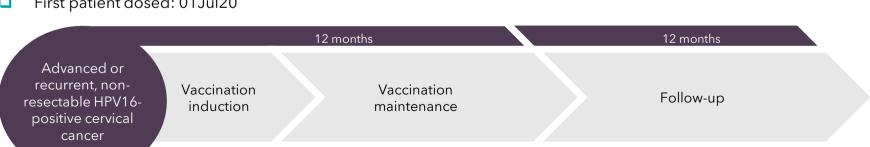
Upregulation of PD-L1 expression in lesions after vaccination



VB C-02: VB10.16 & atezolizumab (Tecentriq®) in advanced Cervical Cancer initiated & on track

A Multi-Centre, Open-label Phase 2a Trial of the Combination of VB10.16 and Atezolizumab in Patients with Advanced or Recurrent, Non-resectable HPV16 Positive Cervical Cancer (NCT04405349)

- Objectives: safety/tolerability, immunogenicity and efficacy
- Primary endpoints: incidence/severity of AEs, ORR (RECIST 1.1.)
- Up to 50 patients
- Conducted in Europe in 6 countries (Germany, Belgium, Bulgaria, Czech Republic, Poland and Norway)
- First patient dosed: 01Jul20



## **Applicability of Vaccibody's Infectious Disease Platform**

	Rapid onset of immune responses	Complex and mulitple antigen design	Tailored to each disease's correlate of protection	Non-complex manufacturing process and formulation, painless administration
Opportunity	One dose efficacy	<ul> <li>Include multiple antigens from same or different pathogens</li> <li>Inclusion of conserved epitopes</li> </ul>	Match targeting unit and antigen to the disease's correlate of protection	<ul><li>Rapid response time</li><li>Global distribution</li><li>Thermostability</li><li>Low CoGs</li></ul>
Applicability	<ul> <li>Pandemics and other emerging diseases, travel, biodefense</li> <li>Therapeutic potential post exposure</li> </ul>	<ul> <li>Vaccine against complex pathogens and pathogens with high Ag variability</li> <li>Pan-pathogen vaccines</li> <li>Immunocompromised patients</li> </ul>	Pathogens particularly sensitive to specific immune responses	<ul> <li>Pandemics and other emerging diseases</li> <li>LMIC</li> </ul>

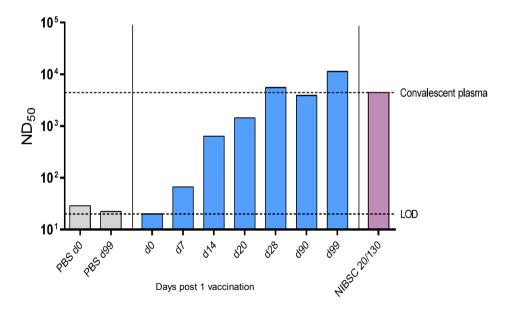


# VB against Covid-19 elicit rapid neutralizing antibody responses 7 days after 1 dose

- Rapid neutralizing Ab responses already at day 7 post 1 dose that increase to day 28
- Stabilizes at high levels without further dosing

Rapid and long-lasting neutralizing activity can be elicited with a single dose

#### Neutralizing Ab responses over time after a single vaccination

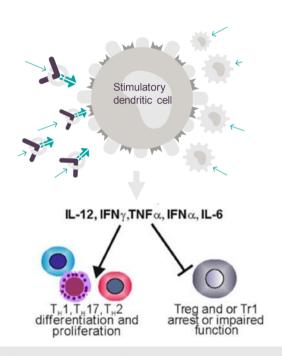


Non-Confidential Norheim\_2020, 22

## Vaccibody's 2-arm strategy to fight variants of concern

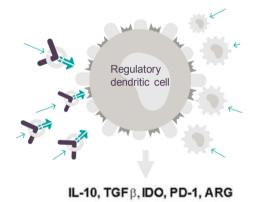
- 1) Rapid development of novel vaccines specifically targeting variants of concern that affect prior immunity as they emerge
  - <u>Candidate 1</u> harbors K417N, E484K and N501Y mutations matching the South African variant of concern
- 2) A T cell-based candidate less sensitive to spike mutations
  - <u>Candidate 2</u> harbors multiple selected, immunogenic and conserved T cell epitopes spanning several SARS-CoV2 antigens
    - Preclinical testing ongoing to identify lead candidate
    - Alone or in combination with RBD/Spike vaccines
    - Prophylactic and therapeutic potential

# Targeting unit offers unique ability to control the Agspecific immune response profile





Natural ligands or scFv binding diverse set of surface receptors



CD4\*, CD8\* conventional T cells proliferation arrest

Cancer and infectious disease

Autoimmunity, allergy etc

vaccibody

## **Key Strengths of Vaccibody™ Platform**

- Flexibility in platform and precision in products
- Improved immune responses
  - Targeting to APC ensure rapid, strong and controlled immune responses
- Safety: very well tolerated across patient groups
- Attractive manufacturing, formulation and administration



# Strong financial foundation for achieving our vision

- By end of the 1st quarter of 2021, Vaccibody had a cash position of USD 179,7 million
- Vaccibody has initiated a process to explore a possible listing on the Nasdaq (US)



## Accomplishments and news flow guidance

#### **Selected accomplishments**

metastatic cancer

- November 2019
  Initial data from the VB10.NEO trial shows positive clinical responses in patients with local or
- July 2020
   First patient dosed in VB C-02 Phase II trial of VB10.16 in combination with Roche's atezolizumab in advanced cervical cancer
- October 2020
  Worldwide, exclusive collaboration with Genentech on VB10.NEO
- December 2020
   Pre-clinical data on second generation Cov2
   vaccine and launch of Infectious Disease strategy

#### **News flow guidance**

- 1H 2021: VB10.COV2 Update on clinical development plans
- 1H 2021: VB10.NEO - initiation of VB N-02, Phase Ib trial
- **2H 2021:** VB10.16 fully enrolled VB C-02 trial in cervical cancer
- VB10.16 interim clinical data for first patients from VB C-02 trial in cervical cancer
- **2H 2021:** Pre-clinical update from the infectious disease initiative



Contact:

**CEO Michael Engsig** 

Vaccibody AS

Cell: +45 6173 1509

mengsig@vaccibody.com



28

# vaccibody -